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Gaining Consent for Carotid Surgery: A Simulation-Based Study of Vascular Surgeons

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Abstract *Aim:* Despite no formal training in consenting patients, surgeons are assumed to be competent if they are able to perform an operation. We tested this assumption for carotid endarterectomy (CEA).
Methods: Thirty-two surgeons [Group 1: junior surgical trainees – performed 0 CEA's ($n = 11$); 2: senior vascular trainees – 1–50 CEA's ($n = 11$); 3: consultant vascular surgeons – > 50 CEA's ($n = 10$)] consented two patients (trained actors) for a local anaesthetic CEA. The performance was assessed at post hoc video review by two independent assessors using a validated rating scale and checklist of risk factors.
Results: There was no difference in performance between the junior and senior trainees (1: median 91 range 64–121; 2: median 100.5 range 66–125; $p = 0.118$ 1 vs. 2 Mann–Whitney). There was a significant improvement between senior trainees and consultant surgeons (3: median 120 range 89–1 142; $p = 0.001$ 2 vs. 3). Few junior (1/11) and senior (2/11) trainees, and most (8/11) consultants, were competent. Inter-rater reliability was high ($\alpha = 0.832$).

Consultant surgeons were significantly more likely to discuss cranial nerve injuries ($p < 0.0001$ Chi-square test) as well as personal or hospital specific stroke risk ($p < 0.0001$) than their junior counterparts. They were less likely to discuss infection ($p < 0.0001$).
Conclusion: Senior trainees, despite being able to perform a CEA, were not competent in consent. The majority of consultant surgeons had developed competence in consenting even though they had no formal training.

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Introduction

Consent is fundamental to good medical practice and clear guidelines for consent are provided by the General Medical

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Council in Great Britain (Table 1). Additionally the argument is made that only those who are capable of performing the surgery should seek consent from the patient, although this is not a legal requirement.[1] The ability of patients to recall and understand information presented to them during the consent process has been assessed, as well as how patients analyse the risk of the procedure following consent.[2–6] There is little in the literature that examines how well doctors actually perform consent-taking, although it is clear that poor consent is implicated in scandals such as the Bristol Inquiry.[7]

There appears to be an assumption that doctors who are able to perform a procedure are able to competently obtain consent. This paper examines this assumption for carotid endarterectomy (CEA).

Methods

Convenience sampling was used to recruit trainee and consultant surgeons to participate in the study. The surgeons were recruited from three groups representative of different experience levels:

1) Group one comprised Junior Surgical Trainees at Senior House Officer level with at least 6 months experience in a vascular surgery placement. They had all participated as an assistant in at least one CEA and had been involved in pre and post operative assessment of CEA patients as well as multi-disciplinary meetings discussing CEA patients.
2) Group two comprised Senior Vascular Registrars who were in the final two years of Vascular Specialist training at tertiary vascular referral centres. All had performed at least one CEA as primary surgeon and had extensive experience of managing patients in the pre and post operative setting.
3) Group three comprised Vascular Consultant Surgeons with experience of more than 50 CEA's as primary surgeon.

Surgeons were asked to undertake two consenting interviews with simulated patients (SPs) whose role involved being scheduled for CEA under local anaesthetic (LA). A full set of patient notes (clinic letters, duplex scan report and clerking sheets) was provided for each patient. Interviews were videotaped for post hoc review and no time constraints were placed on the surgeon.

Table 1 Information to be provided when seeking consent

1) The purpose and details of the investigation or treatment
2) Details and uncertainties of the diagnosis
3) Options for treatment and the likely prognosis, including the option not to treat
4) Explanation of the likely benefits and probabilities of success for each option
5) Known possible side effects
6) The name of the doctor who will have overall responsibility
7) A reminder that the patient can change his or her mind at any time

Three actors were trained to play two SP roles (male and female). The actors were trained according to a validated training protocol for participation in complex simulations.[8]

The surgeons were assessed by two independent reviewers employing a validated information giving rating scale.[9] One assessor was a surgeon and the second was a communications expert. The rating scale covers 19 items, each rated using a 4-point Likert scale. Items are grouped into opening of the consultation, giving of information, process of information and closure. Point three on the 4-point scale corresponding to a judgement of 'competent'.

Item 20 is a judgement of overall impression and uses a 6-point Likert scale (with four on the 6-point scale corresponding to a judgement of 'competent'). For assessment purposes, the scores of both assessors were combined, giving an overall competence score of 114 for the rating scale and 8 for overall impression.

In order to evaluate content of the consenting process for CEA, ten items were identified by expert groups as important for the surgeons to cover in consenting for CEA. These items formed a checklist with dichotomous responses (Table 2). Checklists were cross-referenced with the surgeon's written notes on the consent form to ensure that no items had been missed during video review.

In addition, the surgeons were assessed by the actor, who completed a 5-point Likert rating scale. Items addressed included: opening of the consultation, giving information, closure, whether the patient felt understood and overall satisfaction. Additional space was provided for free text comments.

Statistical Analysis

The data was non-parametric and therefore statistical analysis employs the Mann–Whitney *U* test for comparison between groups, and the Kruskall–Wallis test for comparison across groups. Performance of the groups in different components of the assessment was assessed using the Wilcoxon Signed Rank Test. Inter-rater reliability was assessed using Cronbach's alpha co-efficient.

Results

Thirty-two surgeons were recruited with numbers distributed evenly between the three categories of experience:

- Group 1: Junior Surgical Trainees ($n = 11$);
- Group 2: Senior Vascular Trainees ($n = 11$);
- Group 3: Consultant Vascular Surgeons ($n = 10$)

Time

The consent process took a median of 12 min 04 s (range 5:05–20:00). There was no difference in time taken to complete the consent process between the different groups (group 1: median 18:22, range 6:10–18:22; group 2: median 12:29, range 7:00–12:29; group 3: median 12:57 range 5:05–12:04) $p = 0.272$ Kruskall–Wallis).

Table 2 Risk factors included in analysis of consent (both patients were asymptomatic CEA's)

Item	Comment
Risk of stroke if not operated on from trial data relevant to the patient.	12% in 5 years (asymptomatic)
Risk of stroke from the operation from trial data relevant to the patient.	Reduced by half from approximately 12% −6% based on data from the ACST trial.
Risk specific to individual surgeon/hospital	Local risk 1−2% of stroke/death. Variation accepted. Junior surgeons expected to be aware of their own hospitals audited stroke/death risk and consultant surgeons of their own personal data.
Scarring	Scar site, length
Cranial nerve − voice	
Cranial nerve − tongue	
Nerves to skin/face	Facial drooping/shaving difficulties
Bleeding and related complications	
Infection	Either wound or patch infection
Transfusion	
Other	Myocardial Infarction

Expert Assessment of Consent

Overall score (Fig. 1)

There was a highly significant improvement in performance related to experience (Group 1: median 91 range 64−121; Group 2 median 100.5 range 66−125; Group 3: median 120 range 89−142; $p < 0.0001$ Kruskall−Wallis) on overall assessment using the combined score of the raters (Fig. 1). There was no difference in performance between the junior and senior trainees (Group 1: median 91, range 64−121; Group 2: median 100.5, range 66−125 $p = 0.118$ Mann−Whitney U test), but there was a significant improvement between senior trainees and consultant surgeons (Group 2: median 100.5, range 66−125; Group 3: median 120, range 89−142 $p = 0.001$ Mann−Whitney U test).

On overall consent assessment, the majority of consent procedures performed by junior and senior trainees did not achieve competency, while the majority of consultants were competent (Group 1: 2/22 competent, Group 2: 5/22, Group 3: 16/20). When compared to the overall impression score (Fig. 2) more participants from each group were deemed competent (Group 1: 8/22 competent, Group 2: 14/22, Group 3: 18/20). This difference was significant for both the junior ($p = 0.014$ Wilcoxon signed rank test) and senior trainees ($p < 0.005$) but not for consultant surgeons ($p = 0.157$).

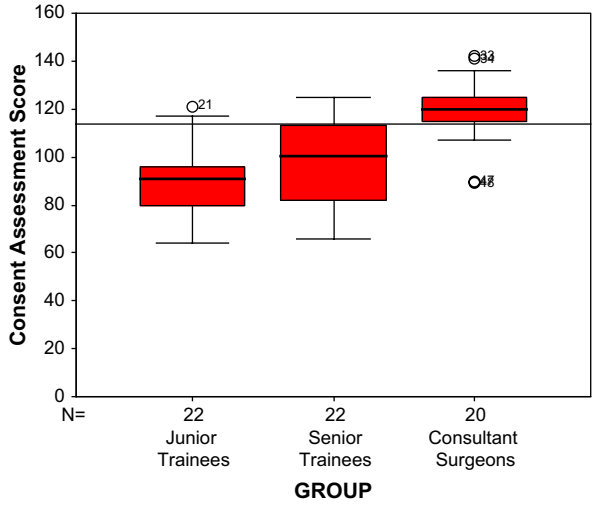

Figure 1 Box plot of overall assessment score by group. The median is represented by a heavy bar, the box represents the inter-quartile range and the whiskers the range. Outliers are shown with a circle and an identifier number. A reference line at a score of 114 denotes a competent score.

Component scores

If the individual component score was analysed there was a significant improvement in performance with increasing experience for all components of the assessment. There was a significant improvement between groups 1 and 2 for the component of giving information only. There was a significant difference between Groups 2 and 3 for all components apart from closure (Table 3).

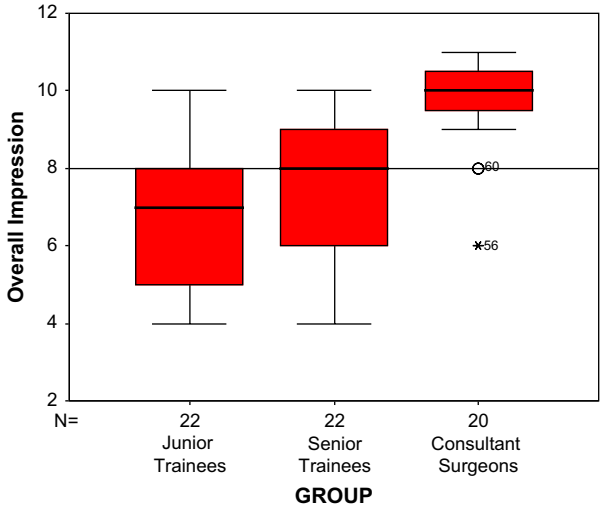

Figure 2 Box plot showing the overall impression score by group. The median is represented by a heavy bar, the box represents the inter-quartile range and the whiskers the range. Outliers are shown with a circle and an identifier number. A reference line at a score of 8 denotes a competent score.

Table 3 Component scores by Group as rated by experts. Median, minimum and maximum values for the component score of the consent assessment for each group. *P* values were calculated using the Kruskall–Wallis test for across group's comparison and the Mann–Whitney *U* test for between groups comparison. Significant *p* values are in bold typeface

	Opening	Giving	Process	Closure
Group 1: median	18.00	26.50	29.50	15.00
Minimum	13	18	21	8
Maximum	28	32	37	28
Group 2: median	19.00	28.00	32.00	17.50
Minimum	13	19	20	8
Maximum	29	35	43	26
Group 3: median	22.50	35.00	41.00	20.50
Minimum	20	30	28	11
Maximum	28	40	46	31
***P* value**	**<0.0001**	**<0.0001**	**<0.0001**	**0.029**
***p* value (1 vs. 2)**	0.146	**0.024**	0.124	0.357
***p* value (2 vs. 3)**	**0.027**	**<0.0001**	**<0.0001**	**0.098**

Simulated Patient Assessment of Consent

The SP assessment score was significantly better for increasingly experienced surgeons for all aspects of patient assessment (Table 4). There was no significant difference between Groups 1 and 2 for any measures, however Group 3 was significantly better than Group 2 on all measures.

The scores as assessed by the SPs showed a strong correlation with assessors ($r = 0.654$ $p < 0.0001$ Spearman's rank order correlation) (Fig. 3).

Inter-Rater Reliability

There was a strong inter-rater reliability between the two assessors for the patient consent assessment ($\alpha = 0.832$).

Risk Factors (Table 5)

Consultant surgeons were significantly more likely than their junior counterparts to discuss potential cranial nerve injuries that could affect the tongue, voice and face ($p < 0.0001$ Chi-square test). In addition, consultant surgeons were more likely to discuss a personal or hospital specific stroke risk with the patient ($p < 0.0001$). Consultant surgeons were less likely to discuss infection than their junior colleagues ($p < 0.0001$). The only difference found between junior and senior trainees was with respect to discussion of nerve injuries to the skin/face ($p = 0.007$ Chi-square test).

Discussion

The results of this study suggest that despite having no formal training in consenting patients, consultant surgeons learn by experience and achieve a level of competency based on this assessment.

The trainees performed poorly in this study. Despite all the junior trainees having had at least 6 months exposure to a vascular unit, and the senior trainees being senior vascular registrars, only a minority achieved a competent score. Of more concern was the significant number of trainees who did not mention cranial nerve injuries as a complication. These are well established side effects of open CEA. According to GMC guidelines, discussing such risks should be part of the consent-seeking process.[10] In addition the legal framework for consent generally accepted in the UK, is that the surgeon should inform the patient of any complications that are generally considered by the speciality to be appropriate.[1] In this study the trainees, both junior and senior, appear to be falling well below this mark.

The consultant surgeons in this study were significantly less likely to discuss infection as a risk of the procedure. Junior and Senior trainees discussed the risk related to wound infection rather than the risk of infection of a prosthetic patch. The consultants that did discuss infection all

Table 4 Component scores by Group as rated by simulated patients. Median, minimum and maximum scores for the components as well as the total patient assessment score. *P* values were calculated using the Kruskall–Wallis Test for across group's comparison and the Mann–Whitney *U* test for between group comparisons. Significant values are in bold typeface

	Introduction	Giving	Closure	Understood	Satisfaction	Total
Group 1: median	3.00	3.00	3.00	3.50	3.00	16.50
Minimum	2	2	2	1	2	11
Maximum	4	4	4	4	4	20
Group 2: median	3.00	3.00	4.00	3.00	4.00	17.50
Minimum	2	2	2	2	2	10
Maximum	4	4	4	4	4	20
Group 3: median	4.00	4.00	4.00	4.00	4.00	20.00
Minimum	3	3	2	3	3	16
Maximum	4	4	4	4	4	20
***P* value**	**0.002**	**<0.0001**	**0.001**	**<0.0001**	**0.003**	**<0.0001**
***P* value(1 vs. 2)**	0.916	0.524	0.068	0.449	0.247	0.499
***P* value (2 vs. 3)**	**0.002**	**0.001**	**0.032**	**<0.0001**	**0.014**	**<0.0001**

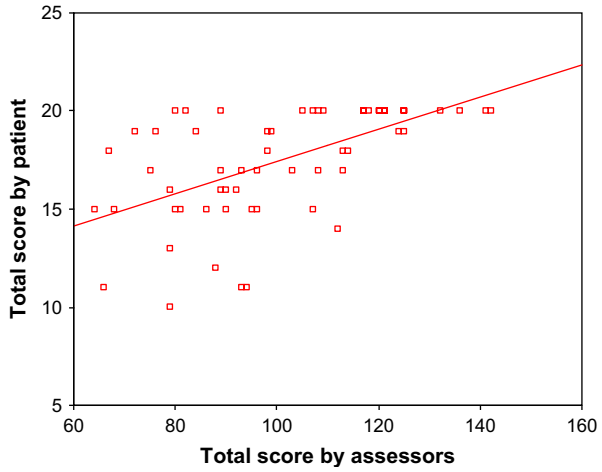

Figure 3 Scattergram showing line of best fit for the correlation between the patients and assessors scores. The *r*-value was 0.654 and *p* value < 0.0001 using Spearman's Rank Order Correlation.

related this to the likelihood of patch infection. Only one consultant surgeon in this study routinely performed eversion endarterectomies. As the need for a patch cannot clearly be established pre-operatively it would be expected that the need for a patch and the potential risks of infection should be discussed as part of a complete consent process.

The poor performance of the junior and senior trainees in this study raises the question of who should be taking consent from patients. In many hospitals, senior registrars would be considered capable of taking consent for this procedure. In this study, all of the senior trainees had performed the procedure at least once themselves and would therefore be considered capable of taking consent.

Table 5 Percentage of surgeons including the listed risk factors in the consenting interview. Statistically significant differences (chi-square test) are highlighted in bold typeface

Item	Group 1	Group 2	Group 3	*p* value
Risk of stroke if not operated on	100%	96%	100%	.379
Risk of stroke from the operation	77.3%	90.9%	100%	.059
Risk specific to individual surgeon/hospital	**36.4%**	**45.5%**	**80%**	**.012**
Scarring	50%	45.5%	45%	.936
Cranial nerve – voice	**40.9%**	**54.5%**	**100%**	**<0.0001**
Cranial nerve – tongue	**59.1%**	**77.3%**	**100%**	**<0.0001**
Nerves to skin/face	**36.4%**	**77.3%**	**100%**	**<0.0001**
Bleeding and related complications	100%	90.9%	95%	.360
Infection	**81.8%**	**81.8%**	**25%**	**<0.0001**
Transfusion	45.5%	45.5%	30%	0.512
Other	36.4%	40.9%	60%	0.506

The ability to perform an operation does not seem therefore, to imply the ability to consent adequately.

Something must be happening between senior trainee and consultant level practice that enables trainees to develop the skills necessary to competently consent patients. We propose that structured training aligned with technical skills training will support the early acquisition of consenting skills by junior and senior trainees.

Limitations of the study

We had a relatively small sample set from a limited sample of training centres. Therefore, participants may not represent the broader surgical community. We only investigated the consenting skills for CEA and do not know if these skills can be extrapolated to other surgical procedures. It is not possible to blind assessors completely to the skill level of surgeons being assessed as clearly older surgeons would be assumed to be consultant surgeons by the assessors which may impact on the results. The a-priori hypothesis of this study was that senior trainees and consultants would be equally competent and therefore the problem of blinding of assessors should not have unduly affected the results.

Conclusions

In summary, this study demonstrates that the majority of consultants are competent in consenting patients for CEA. The majority of trainees have not reached this level of competency. We posit that focused training in consenting may accelerate development of this important skill.

Conflict of Interest

None.

Acknowledgements

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